(i) *Bone solids.* The product's calcium content, measured by individual samples and rounded to the nearest 10th, is more than 130.0 mg per 100 g.

(ii) *Bone marrow.* The product's added iron content, measured by duplicate analyses on individual samples and rounded to the nearest 10th, is more than 3.5 mg per 100 g.[1]

(iii) *Brain or trigeminal ganglia.* Skulls that enter the AMR system have tissues of brain or trigeminal ganglia.

(iv) *Spinal cord.* Vertebral column bones that enter the AMR system have tissues of spinal cord, or the product that exits the AMR system contains spinal cord.

(v) *DRG.* The product that exits the AMR system contains DRG.

(2) If product that may not be labeled or used as ''meat'' under this section meets the requirements of § 319.5 of this subchapter, it may bear the name ''Mechanically Separated (Species)'' except as follows:

(i) If skulls or vertebral column bones of cattle younger than 30 months of age that enter the AMR system have tissues of brain, trigeminal ganglia, or spinal cord, the product that exits the AMR system shall not be used as an ingredient of a meat food product.

(ii) If product that exits the AMR system contains spinal cord or DRG from bones of cattle younger than 30 months of age, it shall not be used as an ingredient of a meat food product.

(iii) If product derived from any bones of cattle of any age does not comply with (c)(1)(i) or (ii), it may bear a common or usual name that is not false or misleading, except that the product may not bear the name ''Mechanically Separated (Beef).''

(3) Spent skulls or vertebral column bone materials from cattle younger than 30 months of age that exit the AMR system shall not be used as an ingredient of a meat food product.

[69 FR 1884, Jan. 12, 2004]

[1] The excessive iron (ExcFe) measurement for an analyzed sample is equal to the obtained iron (Fe) result expressed in mg/100 g measured and rounded to the nearest 100th or more for that sample, minus the product of three factors: (1) The iron to protein ratio (IPR) factor associated with corresponding hand-deboned product; (2) the obtained protein (P) result (%) for that sample; and (3) a constant factor of 1.10. In formula, this can be written as: ExcFe = mFe − IPR × Protein × 1.10, where ExcFe represents the excess iron, expressed in units of mg/100 g; mFe represents the measured level of iron (Fe, mg/100 g), IPR is the iron to protein ratio for the appropriate hand-deboned product, and ''Protein'' is the measured level of protein rounded to the nearest 100th and expressed as a percentage of the total weight of the sample. In lieu of data demonstrating otherwise, the values of IPR to be used in the above formula are as follows: For beef products the value of IPR is equal to 0.104, except for any combination of bones that include any beef neckbone product, for which the value of 0.138 is to be used; for pork product, the IPR value is 0.052. Other IPR values can be used provided that the operator of an establishment has verified and documented the ratio of iron content to protein content in the skeletal muscle tissue attached to bones prior to their entering the AMR system, based on analyses of hand-deboned samples, and the documented value is to be substituted for the IPR value (as applicable) in the above formula with respect to product that the establishment mechanically separates from those bones.

Subparts B–F [Reserved]

Subpart G—Canning and Canned Products

SOURCE: 51 FR 45619, Dec. 19, 1986, unless otherwise noted.

§ 318.300 Definitions.

(a) *Abnormal container.* A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

(b) *Acidified low acid product.* A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

(c) *Bleeders.* Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) *Canned product.* A meat food product with a water activity above 0.85

which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term ''product'' as used in this subpart G shall mean ''canned product.''

(e) *Closure technician.* The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.

(f) *Code lot.* All production of a particular product in a specific size container marked with a specific container code.

(g) *Come-up time.* The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

(h) *Critical factor.* Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) *Headspace.* That portion of a container not occupied by the product.

(1) *Gross headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed containers.* Airtight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container.* A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(2) *Semirigid container.* A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(3) *Flexible container.* A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) *Incubation tests.* Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) *Initial temperature.* The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

(m) *Low acid product.* A canned product in which any component has a pH value above 4.6.

(n) *Process schedule.* The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) *Process temperature.* The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) *Process time.* The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) *Processing authority.* The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) P*rogram employee.* Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see § 301.2(f)).

(s) *Retort.* A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) *Seals.* Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) *Shelf stability.* The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) *Thermal process.* The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

(w) *Venting.* The removal of air from a retort before the start of process timing.

(x) *Water activity.* The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 318.301 Containers and closures.

(a) *Examination and cleaning of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)*—(1) *Visual examinations.* A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to